

Certificate of Mailing [37 CFR 1.8(a)]

1642  
JFW

I hereby certify that this paper and the documents referred to as attached therein are being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Denise Ortega  
Name

November 4, 2004  
Date

Denise Ortega  
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jan Zavada et al.

Serial No.: 09/807,949

Group Art Unit: 1642

Filed : August 9, 2001

Examiner: Christopher H. Yaen

For : MN Gene and Protein

RESPONSE TO OFFICE COMMUNICATION

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is in response to the communication mailed from the U.S. Patent and Trademark Office (PTO) on October 5, 2004 requesting that the Applicants file a statement of the substance of the telephone interview with Primary Examiner Gary P. Nickol, Ph.D. that occurred on September 23, 2004. That telephone interview centered on Applicants' objections to the Advisory Action, mailed from the PTO on September 9, which refused to

enter amendments to the pending claims of the above-identified application.

Claims 31-39, 41 and 42, are pending in the subject application. The Advisory Action refused to enter amendments to those claims because the amendments "raised new issues that would require further consideration and/or search. . . ." The undersigned Attorney for the Applicants had requested an interview with Examiner Christopher H. Yaen and his supervisor, Primary Examiner Gary B. Nickol, Ph.D. Examiner Yaen did speak with the undersigned Attorney for the Applicants and listened to the arguments why the amendments should be entered, but continued to maintain that amendments to independent claim 31, from which the remaining claims depend, would require further searches and new considerations under 35 USC §§ 112, 102 and 103.

Examiner Yaen did state that he would discuss the subject issues with Primary Examiner Nickol. Primary Examiner Nickol then called the undersigned Attorney for the Applicants on September 23, 2004 resulting in the interview summarized below.

#### INTERVIEW SUMMARY

The Attorney for the Applicants presented the following arguments and reasoning why the amendments should be entered.

- (1) The Amendment After Final did not raise any new issues, directly addressed the only remaining rejection, and placed the subject claims in condition for allowance. Section

714.12 of the Manual of Patent Examining Procedure (MPEP)  
was cited:

Any amendment that will place the application  
either in condition for allowance or in  
better form for appeal may be entered.

(2) Reference was made also to the following MPEP sections:

The refusal to enter the proposed amendment  
should not be arbitrary. The proposed  
amendment should be given sufficient  
consideration to determine whether the claims  
are in condition for allowance and/or whether  
the issues on appeal are simplified....If the  
proposed amendment presents new issues  
requiring further consideration and/or  
search, the examiner should provide an  
explanation as to the reasons why the  
proposed amendment raises new issues that  
would require further consideration and/or  
search.

[MPEP §714.13 III, "Action by Examiner".]

Applicant should be notified, if certain  
portions of the amendment would be acceptable  
as placing some of the claims in better form  
for appeal..., if a separate paper were filed  
containing only such amendments.

[MPEP §714.13 III, "Action by Examiner".]

(3) The Applicants submitted amendments to independent claim 31  
in response to the only rejection in the final office  
action, a 35 USC § 112, first paragraph rejection, based  
upon "inadequate written description" of the MN protein  
encoded by a genus of nucleotide sequences. The proposed  
amendment to claim 31 recites the specific binding of MN  
protein to the M75 monoclonal antibody, an antibody that

appeared frequently<sup>1</sup> in the arguments presented by both the

1. In the first Office Action of 2/12/03 at page 4, the Examiner rejected the claims under 35 USC §102(b) as being anticipated by Zavada et al. [Int. J. Oncology, 10(4):857-863 (1997)], which described the M75 Mab, because "Zavada et al teach the identification of an antibody to MN protein which is used to inhibit the binding of human derived cells in a cell adhesion assay. The antibody identified corresponds to an epitope that is located either in the proteoglycan domain or in the carbonic anhydrase domain." Applicants overcame that argument by showing how in the cited Zavada et al. reference, "[b]locking of adsorbed MN protein with an excess of Mab M75 did not abrogate the adhesion of NIH3T3 cells," but required preliminary incubation with SAC cells. It was not until a later reference that the specific binding of the M75 MAb to the MN cell adhesion site was demonstrated. That argument was accepted by the Examiner in the second Office Action of 9/10/03 at page 7.

Also in the second Office Action, the Examiner based a 35 USC §112, first paragraph rejection (at page 5) on the mistaken grounds that "[t]he art teaches that not all antibodies directed against the MN protein are capable of inhibiting the adhesion of MN protein to cells. One such example is Zavada et al (cited previously) wherein it is disclosed that an antibody directed against the MN protein was unable to inhibit the binding of NIH3T3 cells to the MN protein, and only effective upon pre-incubation with SAC." The Applicants had then respectfully pointed out that the instant Specification teaches at page 69, lines 8-13:

"There can be no doubt on the specificity of cell attachment to purified MN/CA IX+. It is abrogated by specific MAb M75, at a dilution 1:1000 of ascites fluid. This is a correction to our previous report in Zavada et al., Int. J. Oncol., 10: 857 (1997) in which we observed that MN/CA IX produced by vaccinia virus vector and fusion protein GST-MN support cell adhesion, but we did not realize that GST anchor itself contains another binding site, which is not blocked by M75."

[Emphasis added.]

The Applicants concluded that "the Specification describes a working example, the M75 Mab to the MN protein, which blocks the cell binding site of the MN protein." The Final Office

Applicants and the Examiner during the prosecution of the application, and also directly addressed the concerns of the Examiner's rejection. Therefore, the Applicants were surprised when the Examiner stated in the Advisory Action of 9/9/04 that the reason for not entering the amendments is that "Applicant amends the claims to recite new limitations in base claim 31, all of which have not been previously searched or considered."

Primary Examiner Nickol discussed the above arguments and reasoning with the Attorney for the Applicants, but agreed with the Examiner Yaen that the amendments required further searches and consideration. The Attorney for the Applicants then

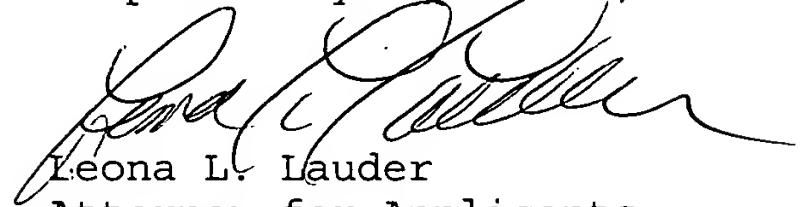
---

Action of 5/17/04 at page 4 indicated that this 35 USC §112, first paragraph rejection was "withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 1/9/2004."

Applicants respectfully concluded that the Examiner was aware of and has considered the binding properties of the M75 monoclonal antibody to the MN protein, and that the M75 Mab was previously accepted by the Examiner as a working example of a molecule that binds to the MN protein, as reflected in the Examiner's statements in the Final Office Action of 5/17/04.

indicated that a RCE would be filed to have the subject unentered amendments examined.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Leona L. Lauder', written in a cursive style.

Leona L. Lauder  
Attorney for Applicants  
Registration No. 30,863

Dated: November 4, 2004